

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

AMERICAN ACADEMY OF
PEDIATRICS, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 8:18-cv-883-DLB

STATUS REPORT

In accordance with the Court's revised remedial order (ECF No. 202), Defendants respectfully report as follows:

1. Covered Applications: This report includes information about "Covered Applications" as defined in Paragraph 7 of the Court's revised remedial order. The FDA has used the same method for determining which applications constitute Covered Applications as it did in its most recent status report (ECF No. 218). Before filing this status report, Defendants conferred with Plaintiffs, who agreed that the set of brands covered by paragraph 7 of the revised remedial order is the same as in that status report.

2. Overall Progress: The FDA remains committed to completing review of the applications it has received as soon as feasible to protect and promote the public health. As projected in Defendants' most recent status report, the FDA took action on 94% of Covered Applications by March 31, 2024. The FDA's best forecast based on current information continues to be that it will take action on all remaining Covered Applications by June 30, 2024, as explained in Defendants' most recent status report.

3. In accordance with the Court's revised remedial order, ECF No. 202, the FDA will file another status report on or before July 22, 2024.

DATE: April 19, 2024

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Respectfully submitted,

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